

Certificate US24/00000343

The quality management system of

CAIRE, Inc.

2200 Airport Industrial Drive, Suite 500, Ball Ground, Georgia, 30107, United States of America

Facility number: F007605

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Brazil: RDC ANVISA n. 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009 - Vigilance

Canada: Medical Device Regulations SOR/98-282, Part 1

Japan: MHLW Ministerial Ordinance No.169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021) Japan PMD Act (as applicable)

USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities

Design, development, manufacturing, distribution and servicing of oxygen concentrators/generators, and liquid oxygen products for home care and professional uses.

This certificate is valid from Effective date 2024-12-17 until Expiry date 2027-12-17 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 2024-08-21

Certified activities performed by additional sites are listed on subsequent pages.

Issue 2. Organization certified since 2018-12-19 and first certified by SGS on 2024-08-21.



Authorised by

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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.



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MDSAP (ISO 13485:2016)

Issue 2

Sites

CAIRE, Inc.
2200 Airport Industrial Drive, Suite 500, Ball Ground, Georgia, 30107, United States of America

Design, development, manufacturing, distribution, repair and servicing of oxygen concentrators and liquid oxygen products.

Campus:
2205 Airport Industrial Drive, Suite 500, Ball Ground, Georgia, 30107, United States of America

Campus:
495 Brown Industrial Parkway, Canton, Georgia, 30114, United States of America

AIRSep Corporation
260 Creekside Drive, Buffalo, New York, 14228, United States of America
Facility number: F007791

Manufacturing, distribution and servicing of oxygen generators, and liquid oxygen products for home care and professional uses in USA only.

CAIRE Medical Technology (Chengdu) Co., Ltd.
1/F, Building 4, No. 670, Haifa Road, Chengdu Cross-Strait Science and Technology Development Park,
Wenjiang District, Chengdu, Sichuan 611138, China

Facility number: F007606
Manufacturing, distribution, service and repair, and customer services.

